DEC 20 2004

K043221

Section E **510(k) SUMMARY**

Submitted by: Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 234-7630 fax
Contact: Gary Phelps

Date Prepared: November 3, 2004

Device Name: **Willi Geller Creation CP Porcelain**
Common Name: Dental Porcelain
Classification: Class II
Product Code: EIH

Predicate Device: Match Press pressable ceramic: 510(k) number K024250

Device Description

Willi Geller Creation CP porcelain consists of pressable ceramic pellets that are used by dental technicians to fabricate full contour restorations (crowns, onlays, inlays, veneers) and substructures for full ceramic demtal restorations that are completed by being veneered with conventional or low fusing dental porcelains. Data has been presented to demonstrate that the mechanical properties, chemical qualities, and the indications for use make ***Willi Geller Creation CP*** substantially equivalent to the predicate device *Match Press pressable ceramic.* The safety and effectiveness of ***Willi Geller Creation Cr***, being determined by the chemical qualities and mechanical properties, is therefore equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2004

Mr. Gary Phelps
Quality Assurance Manager
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K043221
Trade/Device Names: Willi Geller Creation CP Porcelain
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Codes: EIH and ELL
Dated: October 16, 2004
Received: November 22, 2004

Dear Mr. Phelps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

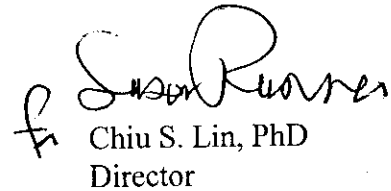
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043221

Device Name: Willi Geller Creation CP Porcelain
Indications for Use:

Willi Geller Creation CP Porcelain is a pressable ceramic material intended for constructing veneer, onlay, inlay, and crown substructures and full contour restorations. Veneering of substructures can be performed with suitable conventional or low fusing dental porcelains such as Willi Geller Creation (K981490) or Willi Geller Creation & LF (K02904).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043221